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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,341	08/01/2003	Stephen Alan Jobling	1770D.	3594

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EXAMINER

PAGE, BRENT T

ART UNIT	PAPER NUMBER
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1638

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07/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/632,341

Applicant(s)

JOBLING ET AL.

Examiner

Brent Page

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-53 is/are pending in the application.
- 4a) Of the above claim(s) 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-43 and 45-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

All arguments not addressed in this office action are considered to be persuasive and the rejections of the previous office action hereby withdrawn.

New Claim 44 is drawn to non-elected subject matter, namely the product of starch, and as it is drawn to non-elected subject matter is withdrawn by the Examiner. The starch of Claim 44 is drawn to new group III.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case Invention III could be made in bacterial hosts, or through synthetic means, and does not require the plant hosts and plant transformation materials required by Invention I.

Applicant is reminded that the election of Group I was made without traverse.

Claims 36-43 and 45-53 are pending and examined on the merits.

The text of those sections of Title 35, US Code not included in this office action can be found in a prior office action.

Claim Rejections - 35 USC § 112

Claims 36-43 and 45-53 are rejected under 35 U.S.C. 112, first paragraph as applied to claims 25, 29-31 and 33-35 in the previous office action mailed 06/28/2006,

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as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The new claims are rejected for the reasons of record of the previous office action mailed 06/28/2006.

Applicants urge that the cited article by Patron et al does not support the Examiner's position that the effect of starch synthase on starch content and structure is unpredictable, and further that Edwards et al deals with differences in amylose with two isoforms of GBSSI which is "clearly different than the focus of the present invention and pending claims".

This is not persuasive because Patron et al does, in fact address starch structure, in observing that it is low in amylose, which affects starch structure; Patron also reveals that different mutations in starch synthase result in differing amounts of amylose and thus, result in unpredictable starch content, and therefore, unpredictable starch structure (see page 190 1st full paragraph, page 191, last full paragraph, page 192, last full paragraph). Furthermore, the breadth of the claims of the present invention would read on different isoforms of GBSSI, as a granule-bound starch synthase, is still a starch synthase and therefore encompassed by the breadth of the claim. Therefore the unpredictability cited by Edwards et al, namely the disclosure of the characterization of the discrete forms of amylose produced by different isoforms of GBSSI in pea (see page 1767, last full paragraph, page 1768 1st and second full

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paragraphs, page 1771 3rd full paragraph, and page 1775 in its entirety), is directly applicable to the current claims. Additionally, even in the case of claim 53, where potato Starch synthase II and potato starch synthase III are specified, there are multiple embodiments of sequences that would be classified as potato starch synthase II and potato starch synthase III. Absent a SEQ ID NO, limiting these DNA sequences to a particular sequence, any unpredictability associated with starch resulting from different sequences encoding the same enzyme directly apply to the claims.

Applicants further urge that the presently claimed invention is not directed to introducing isoforms of starch synthase genes and that in contrast the pending claims are directed to altering starch characteristics produced by a plant by introducing into the plant at least two heterologous nucleic acid sequences, wherein the nucleic acid sequences encode different starch synthase enzymes.

This is not persuasive because the claims do not limit or guide one as to the meaning of "different starch synthase enzymes", and when the broadest reasonable interpretation is applied, any starch synthase enzyme having a different effect and further having even a different sequence, may be interpreted to be a "different starch synthase enzyme", not limited to and including isoforms of a given starch synthase. The Examiner sees no contrast to the two statements above, regarding what the currently pending claims are directed to.

Applicants further urge that citation of Salehuzzaman et al is not relevant to the current invention because it only addresses a single starch synthase gene.

This is not persuasive because the unpredictable starch content as a result of transforming a plant with a single gene is evidence of the unpredictable nature of transforming plants with heterologous starch synthase genes. The cassava GBSSI gene disclosed by Salehuzzaman is heterologous starch synthase gene and is encompassed by the claims as currently written. Applicants mere assertion that the art is not relevant does not constitute a persuasive argument.

Applicants also urge that the transformation of plants with starch synthase enzymes and testing the starch to determine if it meets the claim limitation is routine in the art of plant genetics/breeding.

This is not persuasive because the art has many examples of unpredictability associated with starch content and transgenic plants. Patron et al (Plant Physiology 2002, 130: 190-198) disclose a study detailing the altered pattern of amylose accumulation in low-amylose barley cultivars with mutant alleles of the different isoforms of barley GBSSI (see page 190 1st full paragraph, page 191, last full paragraph, page 192, last full paragraph). Edwards et al (The Plant Cell 2002, 14: 1767-1785) disclose the characterization of the discrete forms of amylose produced by different isoforms of GBSSI in pea (see page 1767, last full paragraph, page 1768 1st and second full paragraphs, page 1771 3rd full paragraph, and page 1775 in its entirety) and Salehuzzaman et al (1999, Plant, Cell and Environment 22:1311-1318) conducted a study in which a cassava GBSSI gene was transformed into an amylose-free potato. Salehuzzaman et al found that amylose content was only partially restored (see page 1313 second full paragraph, for example). The unpredictability and novel discoveries

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cited above are evidence that this, is not, in fact, routine in the art. See *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984) where a significant number of inoperative embodiments was deemed to indicate an undue amount of experimentation.

Additionally, Applicants have not taught the full scope so one would be able to make and use this invention with any starch synthase genes as broadly claimed. Applicants have disclosed **antisense** constructs of **potato starch synthase II** and **potato starch synthase III** that when transformed into **potato**, yield the starch properties claimed by Applicants. Applicants have not taught any other starch synthase constructs whether sense or antisense of any other starch synthase genes, or the above constructs transformed into any other plants that yield the starch properties claimed by Applicants. Absent evidence that other embodiments would in fact, produce the claimed starch properties, and particularly absent the exemplification of any other species or any other starch synthases, Applicants are not enabled for the full scope of the claims as written.

Claims 36-43 and 45-53 are rejected under 35 U.S.C. 112, first paragraph, as applied to previous claims 25, 29-31 and 33-35, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The new claims are rejected for the reasons of record in the previous office action mailed 06/28/06, on pages 5-7.

Applicants urge that a representative number of starch synthase genes have been disclosed in the specification, that a representative number of methods for producing the claimed transformed plants have been disclosed and the methods for analyzing the starch of the transformed plants have been disclosed.

This is not persuasive because the described list only provides for examples of functional equivalents of starch synthase II and starch synthase III. Other starch synthase genes, like starch synthase I or granule bound starch synthase, are not provided for in as much as even a single embodiment.

Applicants also urge that at the time of the filing of the present application, one skilled in the art of plant genetics/breeding who was in possession of Applicants' disclosure would have been able to obtain or isolate a nucleic acid sequence for a variety of heterologous synthase enzymes, transform a variety of plants with such sequences and test the starch obtained from such plants to see if the starch has the characteristics set forth in the pending claims.

This is not persuasive because there are multiple starch synthase genes such as starch synthase I and granule bound starch synthase that are not described in the present application in so much as even a single embodiment, therefore description is not present that would even allow one to identify the essential functional regions of all the available starch synthase enzymes to transform any plant species and test for the starch characteristics as broadly claimed.

Claim Rejections - 35 USC § 102

Claims 36-42 and 45-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Block et al (WO9745545) as applied to claims 25, 30 and 32-35 of the previous office action.

The claims stand rejected for the reasons of record as set forth in the office action mailed 06/28/2006 on page 9 as applied to claims 25, 30 and 32-35.

Applicant's arguments filed 06/28/2006 have been fully considered but they are not persuasive.

Applicants urge that the priority filing date of June 15 1998 obviate the use of Block et al (published December 4, 1997) as a 102(b) reference. This is not persuasive because the rules of applying 102(b) references, state as cited in the previous office action, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, **more than one year prior to the date of application for patent in the United States**. The date of application for patent in the United States in the present application is June 15, 1999, NOT June 15, 1998. The priority date is the date of filing in a foreign country, not in the United States, and therefore does not obviate the use of Block et al as a 102(b) reference.

Applicants further urge that Block et al fail to adequately teach or suggest stably transforming a plant with at least two heterologous nucleic acid sequences each encoding a different starch synthase enzyme so as to produce starch as set forth in the methods and plants of the currently pending claim set.

This is not persuasive because Block et al anticipates all of the claimed method

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steps outlined in the current claim set as stated on page 9 of the previous office action.

Block discloses genetic constructs comprising altered nucleic acids that encode enzymes with starch synthase activity and disclose the alteration of starch content (see paragraph three, pages 5-7 through the middle of page 7, page 13 second paragraph pages 13 last paragraph page 14 in its entirety, page 15 first paragraph, page 16 first paragraph, page 28 last half of page, page 29 in its entirety, for example). Block et al state "Moreover, the present invention also relates to transgenic plant cells transformed with **one or more** nucleic acid molecules of the invention" (see page 13 last paragraph). The nucleic acid molecules of the invention include GBSS I, GBSS II as well as soluble starch synthases. The product is a necessary result of the claimed method steps, absent evidence to the contrary and thus New claims 36-42 and 45-52 are rejected for the reasons of record.

Claim Rejections - 35 USC § 103

Claims 36-42 and 45-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Block et al (WO9745545) as applied to claims 25, 29-31 and 33-35 in the office action mailed 06/28/2006.

Applicant's arguments filed 06/28/2006 have been fully considered but they are not persuasive.

Applicants urge that Block fails to teach or suggest transforming a plant with at least two heterologous nucleic acid sequences each encoding a starch synthase gene so as to produce the starch of the current claim set.

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This is not persuasive because Block et al discloses genetic constructs comprising altered nucleic acids that encode enzymes with starch synthase activity and disclose the alteration of starch content (see paragraph three, pages 5-7 through the middle of page 7, page 13 second paragraph pages 13 last paragraph page 14 in its entirety, page 15 first paragraph, page 16 first paragraph, page 28 last half of page, page 29 in its entirety, for example). Block et al state "Moreover, the present invention also relates to transgenic plant cells transformed with **one or more** nucleic acid molecules of the invention" (see page 13 last paragraph). The nucleic acid molecules of the invention include GBSS I, GBSS II as well as soluble starch synthases. Furthermore Block discloses state "Compared with wild-type starch, such starch may be modified in particular with respect to its viscosity and/or the gel formation properties of the glues of this starch".

No claims are free of the prior art.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (571)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page



ANNE KUBELIK, PH.D.
EXAMINER